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1995 WL 271599 (W.D.Wash.), 35 U.S.P.Q.2d 1225
(Cite as: 35 U.S.P.Q.2d 1225)

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LifeScan Inc.
v.
Polymer Technology International Corp.

U.S. District Court Western District of Washington

No. C94-672R

Decided January 3, 1995
United States Patents Quarterly Headnotes

PATENTS
[1] Infringement -- Construction of claims (Section 120.03)
Infringement -- Literal Infringement (Section 120.05)
Accused blood glucose test strip literally infringes asserted claims for blood glucose test strip, since claims are directed to test strip alone, and not to method of testing blood glucose levels or combination of method and product, since claims are not limited to test strip in monitoring apparatus with whole blood sample present thereon, or to strip in which "optically visible hemoglobin" is found only in blood cells held at surface, since pH levels of accused strip fall within range specified in claims, and since each element of asserted claims is therefore found in accused strip.

PATENTS
[2] Infringement -- Defenses -- License (Section 120.1102)
Purchasers of plaintiff's blood glucose level meters are not impliedly licensed to use defendant's accused blood glucose test strips, since implied license doctrine is limited to method or combination patents and thus does not apply to plaintiff's product patent for test strips alone; implied license defense is unavailable to defendant even if it is assumed that patent in suit is method, rather than product, patent, since defendant has failed to show that there are no non-infringing uses for patented test strip, since circumstances of plaintiff's sale of meters and test strips do not plainly indicate that grant of license to defendant should be inferred, and since implied license, if any, afforded plaintiff's customers would not create implied license for defendant to make and sell patented test strips.

PATENTS
[3] Patentability/Validity -- Specification -- Written description (Section 115.1103)
Patentability/Validity -- Specification -- Claim adequacy (Section 115.1109) Summary judgment that patent in suit is invalid for failure to satisfy requirements of 35 USC 112 is not warranted, since plaintiff has presented evidence that person skilled in art would understand patent specification and claim language, as well as metes and bounds of claims read in light of specification, and since it therefore cannot be held as matter of law that claims and specification fail to sufficiently describe invention of patent.
[4] Patentability/Validity -- Anticipation -- Prior art (Section 115.0703)
Patentability/Validity -- Obviousness -- Secondary considerations generally (Section 115.0907)
Summary judgment that patent in suit is invalid based on anticipation and obviousness is not warranted, since genuine issues of fact exist concerning what may be anticipated or rendered obvious by teachings of prior art references, and since evidence of secondary considerations, such as commercial success, long felt but unresolved needs, and failure of others to invent, weigh heavily in favor of plaintiff on issue of obviousness.

PATENTS
[5] Infringement -- Literal infringement (Section 120.05)
Defendant's use of accused blood glucose level test strips in glucose level meters literally infringes method patents for testing blood glucose levels, since accused test strips fall within language of asserted claims, and since defendant's use of accused test strips in test meters to measure blood glucose levels constitutes practice, and therefore infringement, of claimed methods.

PATENTS
[6] Infringement -- Defenses -- License (Section 120.1102)
Defendant is not entitled to summary judgment that defense of implied license precludes infringement of method patents for testing blood glucose levels using meter to read blood glucose test strip, since there is

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genuine dispute of fact as to whether test meters have non-infringing uses, and since it cannot be held, as matter of law, that grant of license to use accused test strips should be inferred from circumstances of plaintiff's sales of test meters and strips.

PATENTS

[7] Patent Misuse -- In general (Section 140.01)

Defense of patent misuse is unavailable to defendant in action for infringement of patents directed to testing of blood glucose levels using blood glucose test strips and test meter, since test strips, which are subject of one of three patents in suit, are not staple items of commerce, and since charge of patent misuse relating to test strips is therefore precluded by provisions of 35 USC 271(d).

JUDICIAL PRACTICE AND PROCEDURE

[8] Procedure -- Pleadings (Section 410.26)

Patent infringement defendant's motion to amend its answer is denied, since amendments, if allowed, would result in undue delay, since court would need to allow plaintiff additional discovery which would jeopardize current trial date, since amendments would lengthen trial, cause additional scheduling difficulties and delay eventual resolution of case, and since plaintiff would be unduly prejudiced if required to interrupt its trial preparation to undertake discovery or file motions pertaining to proposed amendments.

REMEDIES

[9] Non-monetary and injunctive -- Equitable relief -- Preliminary injunctions -- Patents (Section 505.0707.07)

Patent infringement plaintiff is entitled to preliminary injunction enjoining defendant from manufacturing, selling, or inducing others to manufacture, use, or sell blood glucose test strips for use with plaintiff's glucose test meters, since plaintiff has established reasonable likelihood of success on merits with respect to both validity and infringement, and has demonstrated that it will suffer irreparable harm if defendant is not enjoined, and since balance of hardships and public interest favor issuance of preliminary relief.

REMEDIES

Particular patents -- Chemical -- Blood glucose monitoring

5,304,468, Phillips, McGarraugh, Jurik and Underwood, reagent test strip and apparatus for determination of blood glucose, summary judgment of infringement granted.

5,049,487, Phillips, McGarraugh, Jurik and Underwood, automated initiation of timing of reflectance readings, summary judgment of infringement granted.

4,935,346, Phillips, McGarraugh, Jurik and Underwood, minimum procedure system for the determination of analytes, summary judgment of infringement granted.

***1226** Action by LifeScan Inc. against Polymer Technology International Corp. for patent infringement. On plaintiff's motions for summary judgment of infringement, no implied license and no patent misuse, and for preliminary injunction, and on defendant's motions for summary judgment of patent invalidity, non-infringement and patent misuse, and for leave to amend answer. Plaintiff's motions granted; defendant's motions denied.

Philip S. Johnson, Dianne B. Elderkin, Joseph Lucci, Barbara L. Mullin, and Lynn A. Malinoski, of Woodcock, Washburn, Kurtz, Mackiewicz & Norris, Philadelphia, Pa.; P. Arley Harrel, of Williams, Kastner & Gibbs, Seattle, Wash., for plaintiff.

George W. Neuner, Sewall P. Bronstein, and Kevin J. Fournier, of Dike, Bronstein, Roberts & Cushman, Boston, Mass.; Geoffrey P. Knudsen, of Stoel, Rives, Boley, Jones & Grey, Seattle, for defendant.

Rothstein, C.J.

THIS MATTER comes before the court on the various motions listed below. Having considered the pleadings filed in support and in opposition to the motions, and having held oral argument, the court finds and rules as follows:

I. BACKGROUND

Plaintiff LifeScan, Inc. ("LifeScan") is a corporation which has developed a home use blood glucose monitoring system which is sold commercially, primarily to persons with diabetes who use it to monitor the level of glucose (sugar) in their blood. The meters sold by LifeScan are called One Touch meters, while the strips sold for use in the meters are called One Touch test strips. LifeScan has sought and received patents for various components of its monitoring system. The patents at issue in the pending motions are as follows: No. 5,304,468, ("the '468 patent"); No. 4,935,346, known as ("the '346 patent"); and No. 5,049,487, ("the '487 patent"). This

case concerns claims by LifeScan and defendant Polymer Technology International Corp. ("Polymer") concerning the three above-named patents. Polymer is a corporation which manufactures and sells blood glucose test strips, called First Choice strips, to be used in the One Touch blood glucose meters made and sold by LifeScan.

LifeScan claims that Polymer is infringing its home-use blood glucose monitoring patents. Polymer has presented various defenses to LifeScan's claims of patent infringement, including allegations that the patents themselves are invalid; that users of the LifeScan meters have an implied license to use Polymer's testing strips; and that LifeScan has misused its patents and therefore Polymer is not liable for infringement. In connection ***1227** with their various claims and defenses, the parties have filed the following motions which will be addressed below: LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent; LifeScan's Motion for Summary Judgment of No Implied License for the '468 Patent; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103; LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents; Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents; and LifeScan's Motion for Summary Judgment of No Misuse of the Three Patents at Issue. In addition, Polymer has moved to amend its answers to the complaints which give rise to this matter. Finally, LifeScan has moved for a preliminary injunction with respect to the '468 patent.

II. DISCUSSION

A. *Summary Judgment Standard*

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-50 (1986). The moving party bears the initial burden of demonstrating that it is entitled to summary judgment, *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986), after which the burden shifts to the non-moving party to show that there is a genuine issue of material fact. *Id.* at 322-23. "To create a genuine issue of fact, the nonmovant must do more than present *some* evidence it asserts is disputed." *Avia Group Int'l, Inc. v. L.A. Gear California*, 853 F.2d 1557, 1560 [7 USPQ2d 1548] (Fed. Cir. 1988) (emphasis in original). There must be sufficient evidence presented "favoring the nonmoving party for a jury to return a verdict for that party. If the evidence [of the nonmovant] is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986) (citations omitted); *see also Celotex*, 477 U.S. at 322-23.

B. *The '468 Patent*

The following motions relate to LifeScan's '468 patent, which was issued April 19, 1994: LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent; LifeScan's Motion for Summary Judgment of No Implied License for the '468 Patent; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112; and Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103. The court will address each of these motions in turn.

1. *LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent*

By statute, "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a). Through the patent laws, "Congress [has] recognized that it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the 'useful arts' to expend the time and money necessary to research and develop new products . . ." *Eli Lilly & Co. v. Premo Pharmaceutical Labs., Inc.*, 630 F.2d 120, 137 [207 USPQ 719] (3d Cir.), *cert. denied*, 449 U.S. 1014 [208 USPQ 88] (1980). LifeScan has the burden of proving infringement by a preponderance of the evidence. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054 [5 USPQ2d 1434] (Fed. Cir.), *cert. denied*, 488 U.S. 825 (1988).

The parties agree that in order to determine whether or not a patent has been literally infringed, the court follows a two-step process. *Autogiro Co. of Amer. v. U.S.*, 384 F.2d 391, 401 [155 USPQ 697] (Ct. Cl. 1967). First, the court must ascertain the proper meaning or interpretation of the patent claims themselves. *Id.; see also Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1258 [9 USPQ2d 1962] (Fed. Cir. 1989). In construing the claims, the court should consider, if required, the

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claim language, the other claims, the prior art, the prosecution, and the specification. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1118 [227 USPQ 577] (Fed. Cir. 1985). "The determination of scope of the claims is a question of law, and [thus,] a dispute respecting that legal issue does not preclude summary judgment."*George v.* *1228 *Honda Motor Co., Ltd.*, 802 F.2d 432, 434 [231 USPQ 382] (Fed. Cir. 1986).

After the court has determined the proper meaning or interpretation of the patent claim itself, the next step is to apply the claims to the allegedly infringing device to determine whether that device falls within the scope of the claims. *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673 [15 USPQ2d 1540] (Fed. Cir. 1990). Where the facts underlying the alleged infringement are undisputed, it is the court's function to apply the claims to the accused device. *Martin v. Barber*, 755 F.2d 1564, 1567 [225 USPQ 233] (Fed. Cir. 1985) (citation omitted). If an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. *Graver Tank*, 339 U.S. at 607.

a. Scope of the '468 Patent Claims

The parties dispute whether the '468 patent claims only the testing strips, and thus is a "product" patent, or whether it is a "method" patent or "combination" patent of the strip and meter. This is an issue of law to be determined by interpreting the claims of the patent.

The claims of the '486 patent are quoted below, as they appear in the patent itself.

What is claimed is:

1. A reagent test strip for use in an apparatus for determining the blood glucose concentration of a sample of whole blood, said apparatus comprising optical means for detecting intensity of light at wavelengths of about 635 nm and about 700 nm reflected from at least a portion of said strip by reading the reflectance of at least a portion of said strip;

> said strip having a porous portion disposed near a distal end of said strip such that the porous portion generally registers with the optical means of the apparatus when the strip is retained by the apparatus during determination of said blood glucose concentration, said porous portion having a sample receiving surface for receiving a sample of whole blood and a testing surface, said porous portion further comprising reagent means for indicating the concentration of blood glucose in said whole blood sample in the presence of optically visible hemoglobin by creating a change in reflectance at said testing surface indicative of the concentration of glucose present in said sample, said reagent means comprising chemical reagents selected to produce said change dependent upon the glucose concentration wherein said chemical reagents comprise a dye precursor forming a chromophore indicative of the concentration of glucose present in said sample, said chromophore absorbing light at about 635 nm but not to any significant extent at about 700 nm.

2. The strip of claim 1 wherein said dye precursor comprises 3-methyl-2- benzothiazoline hydrazone hydrochloride and 3-dimethylaminobenzoic acid.

3. The strip of claim 2 wherein the chemical reagents are at a pH of 3.8 to 5.

Claims 1-3, '468 Patent.

Most persuasive to the court on the issue of claim interpretation is the language of the three claims themselves. Claim 1 begins with the words " [a] reagent test strip" while Claims 2 and 3 refer to " [t]he strip of claim 1." It is clear that each claim constitutes a description of the claimed strip, not a claimed method. Each claim provides a detailed description of the makeup and qualities of the claimed strip, not of the method employed in testing blood glucose levels. Claim 1 repeatedly refers to the strip and its characteristics. Mention of the meter in which the strip is used serves to describe certain strip features, not to describe a combination of strip and meter. The mention of the meter apparatus in the first sentence of claim 1 serves' to identify the environment in which the strip will be used, not to create a claim to the method of determining glucose levels in blood or to the combination of strip and meter. *See e.g., Smith Corona Corp. v. Pelikan, Inc.*, 784 F.Supp. 452, 463 (M.D. Tenn. 1992), *aff'd*, 1 F.3d 1252 (Fed. Cir. 1993); *see also In re Stencel*, 828 F.2d 751, 754-55 [4 USPQ2d 1071] (Fed. Cir. 1987).

In addition to the language of the claims, i.e. the repeated references to the strips described in claims 1 through 3, the court finds that the prosecution history favors a finding that the '468 patent is directed solely to the strips themselves. The '468 patent arose out of

a continuation application which was amended to contain new claims directed to a "reagent strip." In June, 1993, these amended claims were amended again, but still directed to a "reagent test strip." Although this amendment, given the number Claim 55, described the apparatus in which it was to be used, the dependent claims added along with Claim 55 each begins with the phrase " [t]he reagent test strip of claim 55 . . ." After considering the amendments of claims 55 through 59, the patent examiner stated that it was "the examiner's position that the *1229 claims are directed to a test strip." Additionally, the examiner referred twice more in that communication to "the claimed test strip." Thereafter, LifeScan submitted an amendment canceling prior claims and adding Claim 60 incorporating the limitations of Claim 55. During and after the submission of Claim 60, LifeScan did not dispute the examiner's interpretation of Claim 55 as referring to the strip itself. In addition, Claim 60 added a feature relating to the nature of the chemicals in the strip.

After an initial rejection by the patent examiner, LifeScan conducted an interview with the examiner, during which drafts of new claims 61 and 62 were discussed. The first of the new claims, which later became claim 1 of the '468 patent, was directed to "a reagent test strip for use in an apparatus for determining the blood glucose concentration in a sample of whole blood." The second new claim, which became claim 2 of the '468 patent, was directed to "the strip of" the first claim. Following the interview, LifeScan also submitted a new claim 63, later claim 3 of the '468 patent, which also was directed to "the strip" of the preceding claim. Claim 61, which was later allowed, contains fewer references to the nature of the apparatus in which the strip is to be used. The references to the apparatus, i.e. the meter, which do exist are merely descriptive of the environment of the intended use of the strip. *See e.g. In re Stencel*, 828 F.2d at 754-55; *see also Smith Corona*, 784 F.Supp. at 463-65. Based on the court's review of the language of the claims and the patent history, the court has determined that, as a matter of law, the '468 patent claims the testing strip and therefore a product, not a method or combination of method and product.

In addition, this court is not persuaded by Polymer's argument that the '468 patent claims are limited to the reagent strip when in place in the meter with a whole blood sample present thereon. This interpretation is simply not supported by the claim language or the claim prosecution.

The court also finds unpersuasive Polymer's arguments concerning the interpretation of claim 3 of the '468 patent, which reads as follows: "The strip of claim 2 wherein the chemical reagents are at a pH of 3.8 to 5." Based on the claim language and the prosecution history, the court finds that the claim language refers to the pH of the chemical reactants in the dry strip, rather than the "pH of all of the chemicals in the strip when it is placed in the meter and a sample of whole blood is applied thereto" as is argued by Polymer.

Finally, based upon the language of the claims and the claim prosecution, the court finds that the language in claim 1 requiring that the porous portion of the strip

compris [e] reagent means for indicating the concentration of blood glucose in said whole blood sample in the presence of optically visible hemoglobin by creating a change in reflectance at said testing surface indicative of the concentration of glucose present in said sample, . . .

does not limit the claim to a strip in which the only hemoglobin that can be optically sensed by the apparatus is that which is "in the red blood cells filtered out and held at the surface of the test strip."

Polymer argues that its strip does not meet the elements of claim 1 because hemoglobin not "in the red blood cells filtered out and held at the surface of the test strip" is optically visible. However, the court disagrees with Polymer's interpretation of the claim language. First, the court finds that there is no indication that the '468 patent claim 1 is limited to a strip in which the only optically visible hemoglobin is that which is in the red blood cells. On this point, the court notes that the patent expressly refers to "blood being analyzed [flowing] through the pores of the matrix" and to "blood . . . wet [ting] the polyamide matrix without having an excess liquid penetrate the porous matrix to interfere with the reflectance reading on the opposite side of the matrix." This language indicates that the claim is not limited to hemoglobin inside red blood cells, but rather also encompasses "free" hemoglobin released into the remainder of the sample. Second, even if the claim were limited in the manner alleged by Polymer, Polymer has not asserted that the hemoglobin presence in red blood cells applied to First Choice strips is not "optically visible" to at least some extent by the LifeScan home-use blood glucose meter.

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Therefore, after reviewing the claim language, the patent specification, the prosecution history, the expert deposition testimony submitted, and the prior art, the court has determined that the proper meaning or interpretation of the '468 patent is that it is directed to the test strips *per se*, rather than to a method or combination of strip and meter. Additionally, the '468 patent claims refer to the strips themselves and are not limited to the strips when in the apparatus, with whole blood upon them. Finally, the phrase "in the present of optically visible hemoglobin" does not limit claim 1 to a strip in which the only hemoglobin optically visible is that which is in red blood cells filtered out and held at the surface of the test strip.

*1230 b. *Application of the Claims to Polymer's Test Strip*

As noted above, the court has determined that the proper interpretation of the patent claim is that the '468 patent is directed to the test strip itself, not the method of testing blood glucose or the combination of the meter and strip. Now the court must apply the patent claims to Polymer's strips, called First Choice test strips, to determine whether the First Choice strips fall within the scope of the '468 patent claims. *See C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673 [15 USPQ2d 1540] (Fed. Cir. 1990). As noted above, if an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. *Graver Tank*, 339 U.S. at 607.

Alleged Disputes of Fact

LifeScan alleges that there is no genuine dispute of material fact concerning the features of the First Choice strips and of the strip claimed in the '468 patent. Polymer alleges that disputes of fact preclude summary judgment on the issue of whether each element of the '468 claims is found in the First Choice strips. The court addresses each of Polymer's factual contentions in turn.

First, Polymer argues that there is a dispute of fact as to whether its First Choice strip functions "just as described in the '468 patent." However, in support of its contention that the "First Choice strip in use functions in a substantially different manner from the strip disclosed and claimed in the ' 468 patent," Polymer simply refers to the declarations of two of its witnesses, an attorney, Gerald Bjorge, and Dr. Callis. This general assertion is insufficient to raise a genuine issue of fact in response to the specific facts submitted in support of LifeScan's motion. In addition, the court has reviewed the cited declarations and finds that they do not support Polymer's assertion of a dispute of fact on this issue, but instead contain disputes as to the legal interpretation of the claim language.

Second, Polymer alleges that there is a dispute of fact as to the pH level of the chemical reagents in its strips. As the court found above, the patent claims a strip with a pH level of 3.8 to 5. As discussed above, Polymer has disputed the claim interpretation, but has not presented evidence disputing LifeScan's statement that "LifeScan's testing of the First Choice strips indicates that the strips are coated at a pH within the range." Finally, at oral argument Polymer did not dispute that its own scientist, Dr. Gleisner, indicated during his deposition that Polymer's strips have a pH level of 4.4 when dry. Thus, the pH level of the First Choice strips falls within the 3.8 to 5 pH range specified in claim 3 of the '468 patent.

Finally, Polymer asserts that there is a factual dispute concerning whether hemoglobin in the red blood cells which is filtered out and held at the surface of the test strip is visible to the optics of the meter apparatus. However, as the court discussed above, the claim is not limited to this interpretation and therefore, Polymer's arguments do not create a material dispute of fact. Rather, Polymer's assertion that its First Choice strip "has substantial free hemoglobin permeating through the porous portion of the strip" places the strip within the claim as interpreted by the court.

Thus, based on the foregoing, the court finds that there is no genuine dispute of material fact precluding summary judgment on the issue of literal infringement of the '468 claims. ii. *Elements of the '468 Patent Claims*

[1] LifeScan has presented undisputed evidence that all of the elements of the claims of the '468 patent are found in the First Choice strips made by Polymer. The court has reviewed the evidence submitted by the parties and compared it to the claim language. Each element of the three claims is found in the First Choice strips. The court finds that there is no limitation on the ' 468 claims requiring the strip to be in place in the blood-glucose monitoring apparatus with a sample of whole blood placed on it. Nor is there a limitation requiring that the "optically visible hemoglobin" be found only in red blood cells held at the surface of the testing strip. Finally, the pH levels of the First Choice strips fall within the range specified in claim 3.

Because each element of the claims of the '468 patent is found in the First Choice strip manufactured and sold by Polymer, the court finds that LifeScan has met its burden on summary judgment. Therefore, LifeScan's motion for summary judgment of literal infringement of the '468 patent is hereby GRANTED.

2. *LifeScan's Motion for Summary Judgment of No Implied License Under the '468 Patent*

***1231** LifeScan sells One Touch meters for home-use blood-glucose monitoring and also sells One Touch testing strips for use in taking blood glucose measurements. LifeScan claims patents on the meters *per se,* (U.S. Patent No. 5,059,394); on the strips *per se,* (the '468 patent); [FN1] and on the methods of making the blood glucose determinations when a testing strip, such as the First Choice or the One Touch strip, is used with a One Touch meter, (the '346 and '487 patents referred to previously in this order). As an affirmative defense to LifeScan's allegations of infringement of the '468 patent, Polymer has asserted that purchasers of LifeScan's One Touch meters are impliedly licensed to use Polymer's First Choice strip and that therefore, Polymer cannot be liable for infringement of the '468 strip patent.

[2] LifeScan moves for summary judgment of no implied license under the '468 patent, [FN2] asserting that the implied license argument is available to Polymer only if the '468 patent is a method or combination patent, as opposed to a product patent. Therefore, if the court determines, as it has above, that the '468 patent is a product patent, LifeScan argues that Polymer cannot raise the defense of implied license. The court agrees that the implied license doctrine is limited to method or combination patents and notes that Polymer has cited no case to the contrary. However, because Polymer expends great effort arguing that an implied license held by the consumers could create a defense to its own infringement liability, the court addresses the argument below.

a. *The Doctrine of Implied License*

The doctrine of implied license was described in *United States v. Univis Lens Co.*, 316 U.S. 241, 249-51 [53 USPQ 404] (1942). In that case, the patent at issue covered multifocal eyeglass lenses. The patent owner sold blank lenses to its licensees. The Court held that when the licensees purchased the blank lenses, they acquired an implied license to complete the lenses through grinding and polishing, thereby practicing the final stage of the patented process. The Court stated that:

. . . it is plain that where the sale of the blank is by the patentee or his licenses -- here the Lens Company -- to a finisher, the only use to which it could be put and the only object of the sale is to enable the latter to grind and polish it for use as a lens by the prospective wearer. An incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, and upon familiar principles the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold. . . .

Id. at 249 (citations omitted).

The parties in this matter cite two Federal Circuit cases which have also addressed the implied license doctrine, *Met-Coil Systems Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 686-87 [231 USPQ 474] (Fed. Cir. 1986) and *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 925 [223 USPQ 982] (Fed. Cir. 1984). In *Bandag*, the owner of a patent claiming a method for retreading tires, Bandag, Inc., sued Al Bolser Tire Stores, Inc. for infringing its patented method of retreading tires by using Bandag equipment which performed the patented methods. Bolser had purchased the equipment from a terminated Bandag franchisee, but was not licensed by Bandag to use it to perform the patented methods. Bolser argued that because Bandag did not prevent the sale of the equipment to a non-franchisee, and because the equipment would need to be modified in order to be used for a non-infringing purpose, that Bolser had acquired an implied license to use the equipment to practice the patented method. *Bandag*, 750 F.2d at 906-07, 924. However, the Federal Circuit Court of Appeals rejected those arguments, stating that "no license can be implied, where as here, the equipment involved has other noninfringing uses, even if only as replacement parts,"*id.* at 924 (citation omitted), and that " [a] mere sale does not import a license except where the circumstances plainly indicate that the grant of a license should be inferred."*Id.* at 925 (citation omitted).

In the second case cited by the parties, *Met-Coil*, the Federal Circuit addressed whether "a patent owner's unrestricted sale of a machine useful only in practicing the claimed inventions presumptively carrie [d] with it an implied license under the patent."*Met-Coil*, 803 F.2d at 685. On the facts of that case, the Federal Circuit court held that the

"patent owner's unrestricted sales of a *1232 machine useful only in performing the claimed process and producing the claimed product 'plainly indicate that the grant of a license should be inferred.' "Id. at 687. Therefore, the court held that " [a]bsent any circumstances tending to show the contrary," the sale of the machine gave Met-Coil's customers "an implied license to practice the inventions claimed in Met-Coil's patent."Id.

Finally, the burden of proving the existence of an implied license is on the accused infringer. Id.

b. *Application of the Implied License Doctrine*

It is evident that there can be no implied license in this case, even utilizing the analysis in the "method" cases. First, Polymer has failed to show that there are *no* noninfringing uses for the test strip claimed in the '468 patent. [FN3] In fact, Polymer itself alleges that its own use of the test strips in setting calibration codes for its strips is a non-infringing use. Second, the circumstances of LifeScan's sale of its meters and test strips do not "plainly indicate that the grant of a license" to Polymer to make and sell the patented test strips "should be inferred."Bandag, 750 F.2d at 925. Finally, the court finds that whether or not LifeScan's *customers* have an implied license to practice the methods claimed in the two patents, the '346 and '487, such a license does not create an implied license for *Polymer* to make and sell the test strips claimed in the '468 patent. [FN4] Polymer's argument that the consumers' alleged right to practice the method patents would be meaningless unless Polymer was granted a corresponding right to make and sell another patented product is frivolous as best.

Therefore, LifeScan's motion for summary judgment of no implied license under the '468 patent is GRANTED.

3. *Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112*

Polymer moves for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112, which provides that the patent

specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Sec. 112, Para. 1. Sec. 112 also requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. Sec. 112, Para. 2.

According to the Federal Circuit, the Sec. 112, Paragraph 1 "written description" requirement exists to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the applicant] was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*"Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 [19 USPQ2d 1111] (Fed. Cir. 1991) (emphasis in original). Sec. 112, Paragraph 2 requires the claims to have a "clear and definite meaning when construed in the light of the complete patent document." Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 [227 USPQ 293] (Fed. Cir. 1985). The test for definiteness under Sec. 112, para. 2 is "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification."Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 [1 USPQ2d 1081] (Fed. Cir. 1986). Compliance with the "written description" requirement of Paragraph 1 of Sec. 112 is a question of fact. Vas-Cath, 935 F.2d at 1563. " [T]he description must clearly allow persons of ordinary skill in the art to recognize what is claimed."Id.

The presumption of validity of a U.S. patent, established by 35 U.S.C. Sec. 282, "requires that the party challenging validity *1233 prove the facts establishing invalidity by clear and convincing evidence."Verdegaal Bros., Inc. v. Union Oil Co. of Calif., 814 F.2d 628, 631 [2 USPQ2d 1051] (Fed. Cir. 1987) (citing American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 [220 USPQ 763] (Fed. Cir.), cert. denied, 469 U.S. 821 [224 USPQ 520] (1984).

In support of its motion, Polymer has alleged numerous deficiencies in the patent specification, the textual description portion of the patent, and a lack of definiteness in the claims which define the "metes and bounds" of the invention. Polymer alleges that the specification does not describe what is meant by the words "in the presence of optically visible hemoglobin;" the specification does not describe that red blood cells from the whole blood sample pass into the pores of the matrix; the specification does not define the term "hematocrit" as meaning

"hemoglobin;" as well as other alleged deficiencies in the specification and the claim language.

Polymer has failed to present any evidence on the issue of how one skilled in the art would understand the language of the specification or the claims of the '468 patent. Instead, Polymer relies on its claim that Dr. Smith is not credible and argues that the indefiniteness and lack of clarity in the specification and claim language is clear on the face of the patent and that the court should, as a matter of law, determine that the patent fails to meet the Sec. 112 requirements.

[3] LifeScan has, with the declaration of Dr. John Smith, LifeScan's Vice President of Research and Engineering, presented factual evidence that one skilled in the art would understand the '468 patent specification and that the specification and claim language is sufficiently clear and definite to meet the requirements of Sec. 112. Additionally, LifeScan has presented evidence, through Dr. Smith, that one skilled in the art would understand the metes and bounds of the claims when read in light of the specification. The court finds Polymer's arguments that Dr. Smith is not credible to be insufficient to overcome LifeScan's presentation of genuine disputes of material fact with respect to this motion. Because the court is unable to say, as a matter of law, that the claim and specification language fails to sufficiently describe the invention claimed, Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112 is hereby DENIED.

4. *Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103*

Polymer moves for summary judgment, arguing that the '468 patent is invalid because claims 1 and 2 of the patent are "anticipated," and claims 2 and 3 are "obvious," in light of prior art. As noted above, the presumption of validity of a United States patent, established by 35 U.S.C. Sec. 282, "requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence."*Verdegaal Bros.*, 814 F.2d at 631 (citation omitted).

a. The Law of Anticipation

The law of anticipation is found in 35 U.S.C. Sec. 102(b). Pursuant to that statute, " [a] person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States,. . . ." 35 U.S.C. Sec. 102(b). A patent claim is anticipated "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."*Verdegaal Bros.*, 814 F.2d at 631 (citation omitted).

b. *The Law of Obviousness*

The law of obviousness is found in 35 U.S.C. Sec. 103, which reads as follows:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art of which said subject matter pertains.

35 U.S.C. Sec. 103. To determine whether an invention would have been obvious at the time it was made, the court must "determine the scope and content of the prior art;" "ascertain the differences between the prior art and the claims at issue;" and "resolve the level of ordinary skill in the pertinent art."*Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 [21 USPQ2d 1053] (Fed. Cir. 1991), (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 [148 USPQ 459] (1966)). In addition, secondary considerations such as "commercial success," "long felt but unsolved needs," and "failure of others to invent," "***1234** are also relevant to the obviousness inquiry." *rYko*, 950 F.2D at 716, (citing *gRaham*, 383 u.S. at 17-18).

c. *Application to the Facts*

Polymer alleges that the '468 patent is invalid because each element of claim 1 is anticipated in European patent application no. 0 140 337 by Dappen (the "Dappen" reference) and in European patent application no. 0 110 173 by LifeScan, Inc. (the "EP '173" reference). Polymer also argues that each element of claim 2 of the '468 patent is anticipated by EP '173. Finally, Polymer alleges that claims 2 and 3 would have been obvious; claim 2 from Dappen combined with the teachings of Ngo, et al. (found at 105 Anal. Biochem. 389-97 (1980)) which allegedly makes the dye couple system of the '468 obvious; and claim 3 from the teachings of Dappen combined with Geoghegan, et al. (found at 60 J. Immuno. Methods 61-68 (1983)) which allegedly would have made the pH range of claim 3 obvious.

In response to Polymer's motion, LifeScan has presented numerous issues of disputed fact underlying the determination of whether the '468 patent claims were anticipated or rendered obvious by prior art. In support of its opposition, LifeScan has submitted the declaration of Dr. Smith, who provides evidence of how one skilled in the art would interpret various aspects of the prior art references as well as the '468 patent. Polymer responds that there is not a dispute of material fact because LifeScan's arguments concern irrelevant issues of fact. Polymer additionally asserts that the court should discount Dr. Smith's testimony and therefore LifeScan's reliance on his testimony. The court will not, on summary judgment, determine the issue of credibility of witnesses. Dr. Smith testified that he was not skilled in the art of the legal interpretation of patent claims, as he is "a scientist, not a lawyer." That testimony does not in any way preclude LifeScan's reliance on Dr. Smith for matters beyond "the legal interpretation of patent claims" including how one skilled in the relevant scientific field would understand the prior art references.

[4] Based on the evidence presented by LifeScan and Polymer, the court finds that there exist genuine disputes of material fact concerning what may be anticipated by, and what may be rendered obvious by, the teachings of the prior art references. These include, but are not limited to, the following: whether one skilled in the art would understand Dappen's "registration layer" to be "porous;" whether the absorbance characteristics of Dappen's dyes are "inherently" those required by the '468 patent claims; whether the greater rate of absorption of light by the Dappen dye system meets the requirement of the '468 patent claims that it not absorb light "to any significant extent at about 700 nm;" whether it is obvious from Dappen or Geoghegan that the dye precursors in Geoghegan should be substituted for those in Dappen; and whether it would be obvious that the appropriate pH level is from 3.8 to 5.

Finally, in addition to the above disputed facts, the court finds that the evidence of so-called "secondary" considerations such as commercial success, long felt but unsolved needs, and failure of others to invent, weighs heavily in favor of LifeScan on the issue of obviousness.

Based on the foregoing, the court concludes that there are genuine disputes of material fact precluding summary judgment on the issues of anticipation and obviousness and therefore Polymer's motion for summary judgment under 35 U.S.C. Secs. 102 (b) and 103 is DENIED.

C. *The '346 and '487 Patents*

The following motions relate to both the '346 and the '487 patents: LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents and Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents.

1. *LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents*

LifeScan alleges that Polymer literally infringes various claims of the '346 and '487 patents. By statute, "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a). In addition, " [w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. 271(b). Finally,

[w]hoever sells a . . . material . . . for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement***1235** of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. 271(c). LifeScan has the burden of proving infringement by a preponderance of the evidence. *Uniroyal, Inc. v. Rudkin- Wiley Corp.*, 837 F.2d 1044, 1054 [5 USPQ2d 1434] (Fed. Cir.), *cert. denied*, 488 U.S. 825 (1988).

As set out above in Section II.B.1, to determine whether or not a patent has been literally infringed, the court follows a two-step process. First, the court must ascertain the proper meaning or interpretation of the patent claim itself. *Autogiro Co. of Amer. v. U.S.*, 384 F.2d 391, 401 [155 USPQ 697] (Ct. Cl. 1967); *see also Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1258 [9 USPQ2d 1962] (Fed. Cir. 1989). In construing the claims, the court should consider, if required, the claim language, the other claims, the prior art, the prosecution, and the specification. *S.R.I. Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1118 [227 USPQ 577] (Fed. Cir. 1985).

After the court has determined the proper meaning

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or interpretation of the patent claims themselves, the next step is to apply the claims to the allegedly infringing device to determine whether that device falls within the scope of the claims. *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673 [15 USPQ2d 1540] (Fed. Cir. 1990). If an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. *Graver Tank*, 339 U.S. at 607.

LifeScan alleges that Polymer literally infringes, or induces its customers to infringe, at least claims 1-3, 6-8, and 10-18 of the '346 patent, which are set forth in Appendix A of this order. LifeScan also alleges that Polymer has literally infringed claims 1 and 2 of the '487 patent, which are set forth in Appendix B of this order.

In response to LifeScan's motion, Polymer alleges that there are disputes of fact which preclude summary judgment of literal infringement of the '346 and '487 patents. However, most of the alleged factual disputes are actually disputes about the legal interpretation of the claim language.

The parties dispute whether Polymer's First Choice strip, and the LifeScan One Touch strip, are composed of single-layer membranes or multi-layered membranes. This court finds that this is not a factual dispute, as the parties agree that the strips are made in the same manner, but rather is a semantic disagreement over the characterization of the resulting strip and the legal meaning of the phrase "single-layer membrane" as used in claims 1, 10 and 15. The strips are created by a technique taught in the patents which consists of "cast [ing] the hydrophilic polymer onto a core of non-woven fibers." The court finds that the resulting membrane, having been cast on a non-woven support, is single-layer. It is undisputed that both strips are formed in this manner. Therefore, the court finds that Polymer's First Choice strips fall within the language of claims 1, 10, and 15.

The parties also dispute the meaning of the phrases "filters out red blood cells" and "exclude red blood cells" found in claims 1, 10, and 15. The court finds that the phrases, properly interpreted, do not require the porous membrane to prevent absolutely all red blood cells from entering the membrane. It is undisputed that both strips do "filter [ ] out" and "exclude" red blood cells.

The remaining issues raised by Polymer in its opposition to LifeScan's motion of literal infringement all purport to be factual disputes. However, the court has reviewed Polymer's statement of disputed facts and finds that all but two of the issues raised by Polymer are legal arguments as to the meaning of the claims or semantic disputes concerning the description of First Choice strips, which do not actually raise any factual issues themselves. The two exceptions are Polymer's statement that the dye product in the First Choice strips absorbs light at the same wavelength that red blood cells absorb light and Polymer's contention that its use of the strips does not involve the practice of the patented methods. However, as to the issue of the rate of light absorption, Polymer's only attempt to create a genuine factual dispute has been to present unsubstantiated affidavit evidence which contradicts the prior sworn testimony of another of Polymer's own witnesses on this issue, without any explanation of the discrepancy. At oral argument, Polymer's counsel did not deny that its expert Dr. Callis had previously testified that the dye product *does* absorb light at a different wavelength than does red blood cells, nor did Polymer's counsel contend that Dr. Callis had been mistaken when he testified concerning his conclusions after conducting a scientific examination. The court finds that Polymer has failed to create a genuine factual dispute on this issue.

As to the second allegedly disputed factual issue, concerning Polymer's use of the strips in a manner which actually practices the patented methods, the court finds that Polymer has failed to rebut the factual assertions ***1236** by LifeScan that Polymer's use of the meters, whether to demonstrate them, or for clinical testing, would constitute practice of the claimed methods. At oral argument, Polymer's counsel failed to deny that Polymer has used the meters to practice the claimed methods. Instead, in Polymer's statement of disputed facts, Polymer focuses on arguing that using the meters to set calibration codes for its strips would not be an infringing use because the meter is not being used to test the amount of glucose, which is already known during the procedure. Whether or not the use of the meter to set the calibration code on the strips constitutes practicing the claimed patented methods, Polymer notably fails to deny that it has used the meters to measure glucose.

Finally, Polymer questions whether LifeScan has presented sufficient evidence showing that the meter, when used, actually practices the claimed methods. The court finds that, through Dr. Smith's testimony, LifeScan has put forth sufficient evidence that use of

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the meters to measure blood glucose does practice the claimed methods and therefore Polymer must come forth with counter-evidence demonstrating that there are genuine issues of material fact on the issue. *See Scripps Clinic & Res. Fdn. v. Genentech, Inc.*, 927 F.2d 1565, 1571 [18 USPQ2d 1001] (Fed. Cir. 1991) (citations omitted). Polymer has not done so. Therefore, the court finds that there is no genuine dispute of material fact concerning whether the meter actually practices the claimed methods, and therefore whether Polymer's use of it thereby infringes the method patents.

[5] In addition, Polymer has failed to rebut the evidence offered by LifeScan that use of the First Choice strips in the meters, when measuring blood glucose levels, infringes claims 1-3, 6-8, and 10-18 of the '346 patent and claims 1 and 2 of the '487 patent, as those claims have been interpreted by the court. Based on this analysis, the court GRANTS LifeScan's motion for summary judgment of literal infringement of claims 1-3, 6-8, and 10- 18 of the '346 patent and claims 1 and 2 of the '487 patent.

The court notes that Polymer has again raised the possibility that the customers purchasing the First Choice strips may have an implied license to practice the methods claimed. However, at this stage, the court is merely determining infringement by Polymer of the claimed methods, not any possible defenses to that infringement. The court has, in this order, denied summary judgment to Polymer on the issue of whether the consumer purchasers of the One Touch meters have been granted an unrestricted implied license to practice the claimed methods because disputed factual issues exist.

2. *Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents*

Polymer has moved for summary judgment of non-infringement of the '346 and ' 487 method patents on the basis of the following argument: only the consumer users of the One Touch meters can directly infringe the method patents (the ' 346 and the '487) because only they practice the claimed methods; the consumers have an implied license to use the meters in their intended fashion; consumers additionally are impliedly licensed to use the meters with First Choice test strips because either the consumer bought a meter without a sticker cautioning the buyer about patent infringement or because the consumer purchased a meter *with* a warning sticker but the stickers are ineffective as a matter of law. Polymer additionally argues that because the consumers are allegedly impliedly licensed to use the meters with First Choice strips, there is no *direct* infringement and therefore Polymer cannot be derivatively liable for inducing or contributory infringement. Finally, Polymer claims it does not practice the method patents itself, and therefore cannot be directly liable for infringement of the method patents.

As set out in detail above, in section II.B.2. of this order, an implied license will only be found when there is no non-infringing use for the article sold (i.e., the only use for the article is one that carries out a patented method or completes a patented combination) and the circumstances of the sale plainly indicate that the grant of a license should be inferred. *Met-Coil Systems Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 686-87 [231 USPQ 474] (Fed. Cir. 1986); *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 925 [223 USPQ 982] (Fed. Cir. 1984). The burden of proving the existence of an implied license is on the accused infringer. *Met-Coil*, 803 F.2d at 687.

[6] The court cannot grant summary judgment on this motion. Life-Scan has presented evidence creating a genuine dispute of fact concerning whether there are non-infringing uses for the One Touch meters. Under *Bandag*, an implied license does not exist if there are non-infringing uses. *Bandag*, 750 F.2d at 924 ("no license can be implied, where as here, the equipment involved has other non ***1237** infringing uses, even if only as replacement parts").

In addition, even if there were no disputes of fact on the issue of non-infringing uses, this court cannot say as a matter of law, on the evidence presented by Polymer, that the circumstances of the sales "plainly indicate that the grant of a license should be inferred."*Met -Coil*, 803 F.2d at 687. The '346 patent issued in June, 1990 and the '487 patent in September, 1991. LifeScan's '468 patent was issued on April 19, 1994. Under United States patent law, a patent owner has no enforceable rights under a patent until the patent issues. *Marsh v. Nichols, Shephard & Co.*, 128 U.S. 605, 612 (1888). LifeScan has presented a genuine issue of material fact as to what expectation customers could have had concerning a license to use a then non-existent patent. Additionally, Polymer has brought forward no evidence of the grant of such an implied license except for the actual sales of the meters, some sold with and some without caution stickers. Notably, no test strips other than LifeScan's strips were authorized by the FDA to be marketed for use with the One

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Touch meter at that time. Additionally, LifeScan has presented evidence of customer literature included in its meter packaging which creates a factual issue concerning the circumstances surrounding the sales of the meters.

With respect to meters sold at later dates, LifeScan has similarly raised genuine disputes of material fact. No strips other than LifeScan's own strips were available for use with One Touch meters prior to the time at which LifeScan began placing stickers cautioning purchasers about patent infringement possibilities. In addition, LifeScan continued placing information in its packaging which creates a dispute of fact concerning the circumstances of the sales and is evidence precluding a finding of an implied license. Finally, Polymer has failed to convince the court that the caution sticker placed on the LifeScan One Touch meters beginning in April, 1993 is ineffectual, as a matter of law, to restrict the use of the meter. At the very least, the sticker language creates a dispute of fact concerning the expectations of a reasonable customer and whether the circumstances of the sales "plainly indicate that the grant of a license should be inferred."*Met-Coil*, 803 F.2d at 687.

Because this court finds that LifeScan has raised genuine disputed issues of material fact in opposition to the motion, Polymer's motion for summary judgment of non-infringement of the '346 and '487 patents is DENIED.

D. *LifeScan's Motion for Summary Judgment of No Misuse with Respect to All Three Patents*

LifeScan has moved for summary judgment on the issue of whether or not there was misuse of the three patents at issue in this case, the '468, the '346 and the '487. Polymer has asserted misuse of the patents as a defense to liability. Patent misuse as a defense refers to inequitable conduct engaged in by the patent owner which renders the patent unenforceable. *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 493-94 [52 USPQ 30] (1942). 35 U.S.C. Sec. 271(d), enacted in 1952, codified the doctrine of contributory infringement and addressed the issue of patent misuse as follows:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

(1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent;

(2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent;

(3) sought to enforce his patent rights against infringement or contributory infringement.

35 U.S.C. Sec. 271(d).

[7] The Supreme Court interpreted Sec. 271(d) in *Dawson v. Rohm & Haas Co.*, 448 U.S. 176 [206 USPQ 385] (1980). In *Dawson* the court held that "the provisions of Sec. 271(d) effectively confer upon the patentee, as a lawful adjunct of his patent rights, a limited power to exclude others from competition in nonstaple goods. A patentee may sell a nonstaple article himself while enjoining others from marketing the same good without his authorization." *Id.* at 201. A nonstaple article is "one which was designed to carry out the patented process and has little or no utility outside of the patented process." *Polysius Corp. v. Fuller Co.*, 709 F.Supp. 560, 576 [10 USPQ2d 1417] (E.D. Pa. 1989). Polymer has presented no evidence disputing LifeScan's claim that the test strips designed for use with LifeScan's One Touch meters are nonstaple items. [FN5] The court finds that the blood glucose test strips are nonstaple items.

***1238** The court notes that in *Dawson* the patentee was permitted to limit competition in the sale of an *unpatented* staple item, whereas here the strip itself is patented, thus making this an even stronger case in favor of a finding of no misuse.

The court is not persuaded by Polymer's arguments that the holding in *Dawson* has been restricted by the enactment of the Patent Misuse Reform act of 1988, codified at 35 U.S.C. 271(d)(4)(5). [FN6] It is clear from the legislative history that Congress intended to extend, not limit, the protection provided by *Dawson*. *See* 134 Cong. Rec. S17146-48 (Oct. 21, 1988) (Amendments enacted to "support [the] enhancement of intellectual property rights" and to "deter misuse claims that unnecessarily burden infringement litigation"). Since the 1988 amendments courts have continued to interpret *Dawson* as this court does here. *See e.g.*, *Joy Technologies Inc. v. Flakt, Inc.*, 1992 U.S. Dist. LEXIS 21720, *8, 24 U.S.P.Q.2d 1150, 1152 (D.Del. 1992), *vacated and remanded on other grounds*, 6 F.3d 770 [28 USPQ2d 1378] (Fed. Cir.

1993); *Alcon Laboratories Inc. v. Allergan Inc.*, 1990 U.S. Dist. LEXIS 13348, *43-44, 17 U.S.P.Q.2d 1365, 1377 (N.D. Tex. 1990); *Polysius*, 709 F.Supp. at 576.

As the court has found that blood glucose test strips are nonstaple items, the court holds that LifeScan has not misused the patents at issue. Therefore, the court hereby GRANTS LifeScan's motion for summary judgment of no misuse of the '468, the '346 and the '487 patents.

E. *Polymer's Motion to Amend Answers*

Pursuant to Fed.R.Civ.P. 15(a) Polymer has moved to amend its answers to the complaints filed in this matter. [FN7] Polymer requests leave to amend its answers in order to add specific allegations of inequitable conduct pleaded as an affirmative defense in this case.

Whether to permit a party to amend its pleading is a matter within the court's discretion. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 330 (1971). The court should consider whether allowing the proposed amendment will cause undue delay, whether it is in good faith, whether it will unduly prejudice the opposing party and whether the amendment may be futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962).

[8] The court has considered the proposed amendments and has determined that if allowed, undue delay would result. The court is convinced that if amendment were permitted the court would need to allow LifeScan additional discovery. The discovery period in this case had passed prior to Polymer's filing of its motion to amend. [FN8] Extensive discovery has already occurred and any further discovery permitted now would jeopardize the current trial date of January 30, 1995. In addition, the court believes that the amendments would cause the trial to be longer than the currently scheduled fifteen-day jury trial, which would cause additional scheduling difficulties, thus delaying the eventual resolution of the entire case. The court also finds that LifeScan would be unduly prejudiced if it were required to interrupt its trial preparation to undertake discovery and/or file motions concerning the proposed amendments. The court notes that the October 13, 1994 deadline for filing dispositive motions passed the same day this motion was filed.

LifeScan argues that Polymer's proposed amendments would also be futile and would not withstand a motion to dismiss. The court has not determined whether or not the amendments would be futile. The trial date in this matter is rapidly approaching and the court does not wish to divert the parties from their trial preparation by requiring an additional round of briefing on the legal sufficiency of the amendments. Finally, the court believes it would be improper to delay the trial in this matter any longer.

***1239** F. *LifeScan's Motion for Preliminary Injunction*

In this motion, LifeScan requests that Polymer be preliminarily enjoined from "manufacturing, using, or selling, or inducing others to manufacture, use, or sell, blood glucose test strips, including the First Choice test strips, for use with One Touch meters, and any other product which infringes LifeScan's United States Letters Patent No. 5,304,468." [FN9]

1. *Legal Standard*

Injunctive relief in patent cases is authorized pursuant to 35 U.S.C. Sec. 283 and under case law. *See e.g., Smith Int'l., Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577-79 [219 USPQ 686] (Fed. Cir. 1983), *cert. denied*, 464 U.S. 996 [220 USPQ 385] (1983). The Federal Circuit has established the following test for determining whether to issue an injunction in patent matters:

. . .to obtain a preliminary injunction, pursuant to 35 U.S.C. Sec. 283, a party must establish a right thereto in light of four factors: (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) the balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest.

These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.

Hybritech Inc. v. Abbott Laboratories, 849 F.2d 1446, 1451 [7 USPQ2d 1191] (Fed. Cir. 1988).

2. *Discussion*

Above, the court has determined that the '468 patent claims the blood glucose test strips themselves, and thus is a product patent, rather than a patent for a method or combination of method and product. The court also determined that Polymer has literally infringed the '468 patent and that LifeScan has not impliedly licensed Polymer under the '468 patent to make, use, or sell the blood glucose test strips.

Additionally, the court found that LifeScan has not misused the '468 patent. Finally, the court found that it could not say, as a matter of law, that the '468 patent as invalid pursuant to 35 U.S.C. Sec. 112, for indefiniteness, or pursuant to 35 U.S.C. Secs. 102(b) and 103, for anticipation and obviousness.

a. *Reasonable Likelihood of Success on the Merits*

According to the Federal Circuit, in order to merit the granting of a preliminary injunction, "a patent holder must establish a likelihood of success on the merits both with respect to validity of its patent and with respect to infringement of its patent." *Hybritech*, 849 F.2d at 1451. As noted, the court has determined, as a matter of law, that Polymer has literally infringed the '468 patent. The court has also determined that LifeScan has not misused the '468 patent, or impliedly licensed Polymer to make, use or sell the blood glucose test strips claimed by the '468 patent. Accordingly, Polymer cannot assert those issues as defenses at trial. However, because the court has not determined whether or not the '468 is valid as a matter of law, [FN10] it remains for the court to consider the likelihood that LifeScan will prevail at trial on the validity issue.

The court has considered the various prior art references cited by Polymer in connection with Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Secs. 102(b) and 103. Having considered this evidence, the court finds that there is a substantial likelihood that LifeScan will demonstrate at trial that the '468 patent claims are not disclosed in the prior art, and are not rendered obvious or anticipated by the prior art references. The court will not be the ultimate finder of fact on that issue; it will remain for the jury to determine. However, for purposes of the motion for a preliminary injunction, the court must weigh the evidence and thus it has *1240 considered whether the claims in the '468 patent would have been anticipated or obvious from the prior art references and concludes that LifeScan has made a strong showing that it will prevail on the issue.

Specifically, the court finds that the following differences alleged by LifeScan are likely to be persuasive to the jury on the issue of whether the strip is novel: most of the prior art relied upon by Polymer was considered by the Patent Examiner prior to his allowance of the '468 patent claims, in particular the court believes that there is persuasive evidence that the European Patent Application No. 0110173A ("the '173 patent") was considered by the Patent Examiner and found not to preclude the '468 claims; the court also finds that LifeScan has presented compelling evidence that the '173 patent does not disclose both a "sample receiving surface" and a "testing surface" and that the Przybylowicz and Clement patents concern "multi-layer strips" unlike the ' 468 single-layer strip; the Przybylowicz and Clement patents do not disclose a reading taken "in the presence of optically visible hemoglobin;" the Dappen reference does not appear to the court to disclose a porous portion as required by the '468 patent; the Dappen reference dye system does not appear to meet the '468 claim requirement that it not absorb light "to any significant extent at about 700 nm; it does not appear that Dappen or Geoghegan teach that the dye precursors in Geoghegan should be substituted for those in Dappen; it does not seem that the references cited by Polymer would make it obvious that the appropriate pH level is from 3.8 to 5, as required by claim 3 in the '468 patent. Thus, based on the court's view of the prior art evidence, LifeScan is likely to prevail on the issues of obviousness and anticipation.

In addition to the above findings concerning the prior art references, the court finds that LifeScan has made a showing of likelihood of success on the issue of validity by presenting considerable objective evidence of non-obviousness of the invention claimed in the '468 patent. Specifically, the court finds that LifeScan has made a strong showing of the following evidence of non-obviousness: the inventions claimed in the '468 strip patent have enjoyed considerable commercial success; Polymer has experienced tremendous growth in sales of its One Touch strips which the court has found above infringe the '468 claims; the improvement in results for the users of the glucose monitoring system which was achieved with non-wipe strips is marked and has contributed to the commercial success; and finally, LifeScan has presented considerable evidence that Polymer developed its First Choice strips by following the '468 patent claims and disclosure. Based on the objective evidence presented by LifeScan on the issue of non-obviousness, the court finds that LifeScan has made a strong showing that it is likely to succeed on the issue of obviousness at trial.

Finally, the court finds that LifeScan is likely to prevail at trial on the issue of validity under 35 U.S.C. Sec. 112, which requires definiteness in the claim and specification language. Although the court found above that there remained disputed issues of fact, the court had considered the evidence presented by both sides on the issue and is of the opinion that

LifeScan is more likely to prevail on the issue of whether, through the testimony of Dr. Smith, the '468 description would allow one skilled in the art to recognize what is claimed.

Therefore, the court finds that LifeScan has shown a likelihood of success on the merits of the issue of validity. As the court has already found that Polymer has infringed the '468 patent as a matter of law, LifeScan has "establish [ed] a likelihood of success on the merits both with respect to validity of its patent and with respect to infringement of its patent." *Hybritech*, 849 F.2d at 1451.

b. *Irreparable Harm*

The court makes the following findings with respect to the issue of irreparable harm: LifeScan did not delay in seeking a preliminary injunction with respect to the infringement of the '468 patent as it filed its preliminary injunction motion (in an action in the Eastern District of Pennsylvania) on the *same day the '468 patent issued*, April 19, 1994; LifeScan's grant of a license to Can Am, another strip manufacturer, does not negate the possibility of irreparable harm caused by Polymer's actions; Polymer's sales have increased dramatically over the past eight months; Polymer has captured a substantial portion of the market in test strips over the past months; LifeScan is losing market share to Polymer; Polymer's assets are insufficient, based upon the testimony of Polymer's chief financial officer Ms. Helenick, to satisfy the damages LifeScan will be able to claim if it prevails on the merits at trial; and LifeScan is likely to lose good will with its customers because of the pricing difference between One Touch and First Choice strips. Therefore, based on these findings, the court holds that LifeScan has demonstrated that it will suffer irreparable harm if Polymer is not enjoined.

***1241** c. *The Balance of Hardships*

The court finds that the balance of hardships tips in favor of LifeScan. LifeScan cannot recover from the irreparable harm outlined above even if it prevails at trial. Additionally, LifeScan has offered to post a bond sufficient to cover any potential damages suffered by Polymer due to an injunction. Although the court recognizes that Polymer and its employees will be harmed substantially by an injunction, it is persuaded that such harm is less than that which would be suffered by LifeScan if Polymer continued producing and selling the First Choice strips.

d. *Impact on the Public Interest*

The court finds that although there are advantages to the public in being able to purchase low-cost medical products, the public interest favors the granting of an injunction in favor of LifeScan. Congress has determined that "it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the 'useful arts' to expend the time and money necessary to research and develop new products." *Eli Lilly & Co. v. Premo Pharmaceutical Labs., Inc.*, 630 F.2d 120, 137 [207 USPQ 719] (3d Cir.), *cert. denied*, 449 U.S. 1014 [208 USPQ 88] (1980) (citations omitted). Congress has made the legislative determination that it is not in the public interest to permit the infringement of those temporary monopolies as it undermines inventor incentive.

e. *Conclusion*

[9] Having balanced the relevant factors, and having considered all of the evidence presented by the parties, the court finds that LifeScan has demonstrated that it is entitled to a preliminary injunction prohibiting Polymer from "manufacturing, using, or selling, or inducing others to manufacture, use, or sell, blood glucose test strips, including the First Choice test strips, for use with One Touch meters. For security, pursuant to Fed. R. Civ. P. 65, LifeScan shall file with the Clerk of this court a surety bond in the amount of $5,000,000. within five working days of this order.

III. CONCLUSION

Based on the foregoing, the court hereby rules as follows:

1) the court GRANTS LifeScan's motion for summary judgment of literal infringement of the '468 patent;

2) the court GRANTS LifeScan's motion for summary judgment of no implied license under the '468 patent;

3) the court DENIES Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112;

4) the court DENIES Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Secs. 102(b) and 103;

5) the court GRANTS LifeScan's motion for summary judgment of literal infringement of the '346 and '487 patents;

6) the court DENIES Polymer's motion for summary judgment of noninfringement of the '346 patent, and the '487 patents;

7) the court GRANTS LifeScan's motion for summary judgment of no misuse of the '468 patent, the '346 patent, and the '487 patent;

8) the court DENIES Polymer's motion to amend its answers; and

9) the court GRANTS LifeScan's motion for a preliminary injunction concerning the '468 patent.

Appendix A

'346 Patent Claims 1-3, 6-8, and 10-18

1. In a method for determining glucose in a blood sample employing a membrane and a signal-producing system which reacts with glucose to produce a light-absorptive dye product, said system being bound to the membrane, and in which the amount of said dye product is determined by means of a reflectance measurement from a surface of said membrane, an improvement which comprises:

applying an unmeasured whole blood sample to a first surface of a single-layer, substantially reflective, porous, hydrophilic membrane having pores of a size sufficient to exclude red blood calls and which contains said signal-producing system;

making said reflectance measurement on a second surface of said membrane other than the surface to which said sample is applied without removing excess sample or red blood cells from said first surface; and

*1242 determining the concentration of glucose in said sample from said reflectance measurement.

2. A method according to claim 1, wherein said signal-producing system produces a dye product which absorbs light at a wavelength different from a wavelength at which said red blood cells absorb and said reflectance measurement is made at two different wavelengths, one absorption wavelength reflectance measurement to correct for background absorbance due to red blood cells and the other reflectance measurement at the absorption wavelength of said dye product.

3. A method according to claim 2, wherein said two wavelengths are at about 635 and 700 nm.

6. A method according to claim 1 wherein said membrane comprises polyamide and said signal producing system comprises glucose oxidase, peroxidase, and 3- methyl-2-benzothiazolinone hydrazone/3-(dimethylamino)benzoic acid.

7. The method of claim 1, wherein said pores have an average diameter of from about 0.1 to about 3.0 um.

8. The method of claim 1, wherein said membrane consists essentially of polyamide and has a thickness of from about 0.01 to about 0.5 mm.

10. A method for determining glucose comprising the sequential steps of:

(a) applying a whole blood sample to an application site on a reagent element wherein said reagent element comprises a single-layer, substantially reflective, porous, hydrophilic matrix which filters out red blood cells and to which is bound a signal-producing system comprising glucose oxidase, peroxidase, and a dye indicator, which signal-producing system reacts with glucose to form a reaction dye product;

(b) allowing the sample to migrate to a reading site on said membrane different from said application site;

(c) monitoring reflectance at said reading site for a decrease in reflectance indicative of sample presence in said reading site in order to initiate timing of an incubation period; and

(d) determining the change in reflectance at said reading site during the incubation period as a measure of dye product formed to determine the amount of glucose in said sample wherein

all reflectance measurements at said reading site are performed without removing excess sample or red blood cells from said application site and at least one measurement is taken at a wavelength at which light is absorbed by said dye product.

11. A method according to claim 10, wherein said dye indicator is 3-methyl-2-benzothiazolinonehydrazone/3 -(dimethyl-amino)benzoic acid.

12. A method according to claim 10, wherein said hydrophilic membrane comprises a polyamide.

13. A method according to claim 12, wherein said hydrophilic membrane is positively charged.

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(Cite as: 35 U.S.P.Q.2d 1225)

14. The method of claim 10, wherein said determination of the amount of glucose in said sample further includes determining the change in reflectance at a second wavelength to provide a correction for background absorbance at the dye product absorbing wavelength due to an interfering substance in said sample.

15. A method of determining analyte concentration in a liquid, which comprises:

quantitatively measuring baseline reflectance from a first surface of a reagent element comprising an inert, porous, hydrophilic, substantially reflective, single-layer matrix having pores of a size sufficient to exclude red blood cells and a reagent system which interacts with said analyte to produce a light-absorbing reaction product, said reagent system being impregnated in the pores of said matrix, prior to application of said liquid to said reagent element; applying said liquid to a second surface of said reagent element and allowing said liquid to migrate from said second surface to said first surface;

quantitatively measuring reaction reflectance from said first surface of said reagent element without removing excess sample or non-migrating components of said sample from said second surface;

quantitatively measuring reflectance of interfering substances from said first surface of said reagent element using a wavelength of light reflected by interfering substances and different from the wavelength of light used to measure said reaction product reflectance in order to correct for background reflectance at the reaction product wavelength caused by interfering substances; and calculating a value expressing said analyte concentration from said reflectance measurements.

16. The method of claim 15, wherein said matrix comprises a polyamide.

17. The method of claim 15, wherein the average diameter of the pores in said matrix is from 0.2 to 1.0 um and said liquid is whole blood.

***1243** 18. The method of claim 17, wherein said analyte is glucose, and said reagent produces a light-absorbing reaction product upon reacting with glucose.

Appendix B

Claims 1 and 2 of the '487 Patent

1. A method of causing an analytical measurement to be made in a reflectance-reading device at the end of a predetermined time period after an analyte reacts with a reagent in a porous, reflectance-reading matrix located in said device, which comprises:

taking a first reflectance reading from a dry first surface of said porous matrix prior to application of a sample of body fluid suspected of containing said analyte to a second surface of said porous matrix from which said sample can travel to said first surface by capillary action and react with said reagent in said porous matrix if said analyte is present in said sample;

applying said sample to said second surface of said porous matrix;

taking an additional reflectance reading from said first surface after said sample is applied to said porous matrix;

comparing said additional reflectance reading to said first reflectance reading;

initiating said predetermined time period upon a predetermined drop in reflectance sufficient to indicate that said sample has reached said first surface; and

taking a measurement reflectance reading at the end of said predetermined time period without having determined the time at which said sample was initially applied to said porous matrix.

2. A method according to claim 1, wherein said reagent comprises a dye precursor bound to the matrix.

FN1 The court has determined above that the '468 patent refers to the "reagent test strip" itself and is not a method or combination patent.

FN2 LifeScan's motion for summary judgment of no implied license is directed to the '468 patent only. The issue of implied license with respect to the method patents, '346 and '487, is addressed in the motion by Polymer concerning non-infringement of the two method patents.

FN3 Polymer argues that there are no *substantial* noninfringing uses for the strip other than to practice the method patents.

LifeScan argues that the standard is whether there are *any* noninfringing uses and alleges that there are indeed noninfringing uses for the meters, including using the meter to measure glucose in substances other than blood.

FN4 LifeScan alleges infringement of the '468 patent not simply due to the use of the test strip by the consumer meter-users, but due to Polymer's activities, pursuant to 35 U.S.C. Sec. 271(a) which states that " [e]xcept as otherwise provided in this title, whoever without authority *makes, uses* or *sells* any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a) (emphasis added).

FN5 Polymer's claims that the meter purchasers are impliedly licensed to use other brands of strips does not create a substantial non-infringing use, rather it would provide the infringing consumer with an implied license defense to infringement liability. *See generally, Dawson*, 448 U.S. 176 [206 USPQ 385] (1980).

FN6 35 U.S.C. Secs. 271(d)(4) and (5) read as follows:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: . . . (4) refused to license or use any rights to the patent; or

(5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or the patented product on which the license or sale is conditioned.

FN7 This matter results from the consolidation of two complaints. Polymer has filed two answers, one to each of the complaints.

FN8 The discovery period in this matter ended on October 4, 1994. Polymer filed the motion to amend its answers on October 13, 1994.

FN9 This motion comes before the court on remand from the Federal Circuit. The Federal Circuit vacated this court's June 9, 1994 order denying LifeScan's motion for a preliminary injunction. *See LifeScan v. Polymer*, Docket No. 94-1369 (Fed. Cir. Oct. 18, 1994). Because the initial order has been vacated, the court intends for this order to supersede the June 9, 1994 order.

FN10 Finding the existence of genuine disputes of material fact, the court has denied Polymer's two motions for summary judgment of invalidity of the '468 patent.

W.D.Wash.

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1990 WL 18681 (E.D.Pa.), 15 U.S.P.Q.2d 1856
(Cite as: 1990 WL 18681 (E.D.Pa.))

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Motions, Pleadings and Filings

United States District Court, E.D. Pennsylvania.
ORTHO PHARMACEUTICAL CORP.
v.
Herchel SMITH, American Home Products Corporation, et al.
CIV. A. No. 90-0242.

Feb. 23, 1990.

Albert G. Bixler, Daniel Segal, Hangley, Connolly, Epstein Chico, Foxman & Ewing, Philadelphia, Pa., for plaintiffs.

Stephen B. Judlowe, Marguerite Del Valle, Joseph Mazzarese, Hopgood, Calimafde, Kalil Blaustein & Judlowe, New York City, pro hac vice, for plaintiffs.

Steven R. Petersen, Michael T. Scott, Reed, Smith, Shaw & McClay, Philadelphia, Pa., for American Home Products Corporation.

Paul H. Heller, Kenyon & Kenyon, New York City, pro hoc vice, for defendants.

FINDINGS OF FACT CONCLUSIONS OF LAW

NEWCOMER, Senior District Judge.

I. *FINDINGS OF FACT.*

*1 1. Ortho Pharmaceutical Corporation ("Ortho") is a company organized under the laws of the State of Delaware with its principal offices in Raritan, New Jersey. Ortho is a wholly owned subsidiary of Johnson & Johnson ("J & J").

2. Defendant Herchel Smith is the owner of record of United States Patents 3,850,911 ('911) and 3,959,322 ('322); American Home Products Corporation ("AHP") and its Wyeth-Ayerst Laboratories division ("WAL") are the exclusive licensees under the '911 and '322 patents.

3. Ortho and AHP are competitors in the oral contraceptive business in the United States (about $1-Billion annual sales). Ortho has the largest market share. AHP has the second largest market share.

4. This dispute centers on Ortho's right to market an oral contraceptive containing norgestimate, a compound AHP contends falls within certain claims of the '911 and '322 patents.

5. In the late 1950's Herchel Smith and Gordon Hughes invented a synthesis of a whole series of novel 13-polycarbon substituted gon-4-ene steroids, as described in their '322 patent. Their discovery that certain 13-ethyl compounds were potent progestins with novel properties opened a new area to synthetic organic chemists. Within a few years many pharmaceutical companies around the world were developing the 13-ethyl gon-4-enes.

6. Even today the only totally synthetic steroids which are available commercially are the 13-ethyl-gon-4 enes, norgestrel, gestodene, desogestrel, and norgestimate. They all fall within the scope of claims 5, 40, or 43 of the '322 patent. All other steroids continue to be manufactured by chemical modification of naturally occurring steroids. (Goldzieher I ¶ ¶ 19-20, glossary)

7. At the time of Ortho's introduction of norgestimate-containing products in each foreign country (from 1986 to 1989) there were no unexpired AHP patents covering norgestimate. At no time did Ortho ever introduce a norgestimate-containing product where such action would infringe an AHP patent still in force. (Wiser ¶ ¶ 7, 9)

8. In January 1989, a research bulletin indicated that Ortho was expecting FDA approval of a product containing norgestimate in late 1989 or early 1990. (Wiser ¶ 11 and Exhibit B thereto). Applications for new drug approval (which are held in confidence) may be based on foreign clinical trials or trials in the United States solely for Food and Drug Administration (FDA) approval, neither of which constitutes acts of patent infringement. The research bulletin does not identify any activity which constitutes an act of patent infringement. (Bjorge II ¶ ¶ 12-14, Victoria ¶ 17).

9. In February, 1989, as a result of the publicity of Ortho's norgestimate product, AHP through its attorney, contacted J & J. AHP advised Ortho that if norgestimate was marketed in the U.S. before the expiration of the Smith patent in November 1991,

that AHP would enforce its patent. AHP also sought to determine whether any of Ortho's acts to date constituted infringement. Ortho's position was that it had not infringed, but would give no assurances concerning its future actions. Ortho indicated that the bulletin was optimistic and that Ortho had not yet decided what its market plans were. (Wiser ¶ ¶ 13-23, Berg Dep. 20, 29-31, 37, 40.)

*2 10. The parties exchanged various views on the issues of validity and infringement during meetings in March and May of 1989. At these meetings, AHP sought certain assurances from Ortho regarding any marketing of, or activities relating to, a norgestimate product. Ortho refused to give any such assurances. However, the parties reached agreement in principle that a mediator would be appointed to review, in confidence, Ortho's activities, to determine if infringement had occurred, or whether Ortho's activities were exempt under 35 U.S.C. § 271(e)(1). AHP was to prepare a draft mediation agreement and forward it to Ortho for review. (Wiser ¶ 15, 22, 24, Berg Dep. 26, 40-41).

11. Ortho assured AHP that its forbearance from litigation would not prejudice AHP in any future litigation, and this assurance was embodied in the draft mediation agreement sent to Ortho in August, 1989 (Wiser ¶ ¶ 126, 27, 30, Exhibit D thereto, ¶ 17). In September, 1989, Ortho wrote to AHP agreeing in principle with AHP's draft, but expressing a desire to "simplify" it to keep the costs down. (Wiser ¶ 28, and Exhibit F thereto). In further discussions in October and December 1989, Ortho told AHP that it was revising the draft agreement. At no time did Ortho indicate that it did not intend to go ahead with this agreement, nor that FDA approval was imminent. (Wiser ¶ 29). However, throughout this period Ortho intended to market norgestimate as soon as it received FDA approval. (Hilke at 79, 91). I find that, AHP did not delay in enforcing its patent rights.

12. On December 29, 1989, the Food and Drug Administration approved Ortho's New Drug Application to market Ortho-Cyclen, an oral contraceptive product containing norgestimate.

13. On January 11, 1990, Ortho commenced the underlying lawsuit seeking a declaratory judgment that the '911 and '322 patents are invalid.

14. On January 20, 1990, AHP counterclaimed against Ortho for infringement of AHP's patent rights, naming J & J as an additional defendant, and moved for this preliminary injunction.

15. Ortho has admitted infringement of claims 40 and 43 (Ortho Response at 23), and AHP alleges that Ortho infringes claim 5 of the '322 patent either literally or under the doctrine of equivalents. (Victoria ¶ , Bjorge I ¶ B-14, Goldzieher I ¶ 32). [FN1]

16. In 1968, the United States Food and Drug Administration (FDA) first approved the commercial sale of AHP's norgestrel. Norgestrel met the long-sought needs of the medical community for oral contraceptives with smaller doses of sex hormones (giving the same contraceptive effect). AHP's product was initially greeted with some skepticism. Doctors were doubtful that an oral contraceptive could be effective at such low doses while maintaining cycle control. (Rachelli ¶ 10-17). The FDA recommends that "all women who take oral contraceptives should take the lowest possible dose formulation that is effective." (Victoria Exhibit A, p. 2). Annual sales of norgestrel-containing products in the United States from 1968-1989 were approximately 2.4 billion dollars. In 1989, sales of AHP's norgestrel-containing products were approximately 300 million dollars (approximately 35 percent of the total sales of oral contraceptives). (Rachelli ¶ ¶ 22-23).

*3 17. AHP's norgestrel products have been widely accepted and prescribed. AHP holds close to 70% of the total contraceptive market overseas, where sales of AHP's oral contraceptives were about 7.4 times as large as sales in the U.S. on a unit basis, in 1989. (Novinski ¶ 6, Table A thereto). The total sales of all norgestrel-related products, i.e. norgestrel, levo-norgestrel, gestodene, norgestimate, and desogestrel amounted to 92.5 percent of all oral contraceptives sold in 1989, outside the United States. (Novinski ¶ 8, Table B).

18. Throughout the 15 year life of the Smith patents, the industry has respected AHP's patent rights in norgestrel and norgestrel-related compounds. Several major pharmaceutical companies, both domestic and foreign, were actively developing products in this area before the '322 patent issued. Neither those companies, nor other companies which have since developed norgestrel-related compounds, have attempted to market those compounds in the United States during the lifetime of the '322 patent. (Rachelli ¶ 21, 47). The Smith patents were challenged in several opposition proceedings abroad and interferences in the United States. None were

successful. (Wiser ¶ 9.)

19. AHP has granted a royalty-veering, non-exclusive license in the United States under AHP's '322 patent for norgestrel to Berlex Laboratories, Inc. (Rachelli ¶ 18). Berlex is owned by Schering A.G.

20. There was no defect or informality in the examination or issuance of the Smith patent. On the contrary, the application for the Smith patent received close and careful scrutiny by experienced Patent Examiners and by four panels of the Patent Office Board of Patent Interferences. There are no indications in the prosecution history that the application in any way failed to comply with all requirements of the Patent Statute. AHP's '322 Patent therefore stands as a presumptively valid United States patent, properly issued by government officials presumed to have done their job correctly. (French ¶ 3, 8-11, 13, 15; Bjorge I ¶ C-12).

21. Ortho has argued that certain Belgian patents contain compounds which fall within the generic claims of the '322 patent. This is incorrect (Bjorge II ¶ 6). In addition, the compounds of the Belgian patents differ significantly from those of the '322 patent. (Smith ¶ ¶ 16, 18).

22. The Belgian patent, like Bachmann (a reference brought to the attention of the Patent Office, but not considered sufficiently relevant to be relied upon to reject the claims (French ¶ 16)), discloses compounds with an aromatic A-ring. The Patent Office recognized that compounds with aromatic A-rings are a separate, independent and distinct invention from the gon-4-enes of the '322 patent. (Bjorge II ¶ ¶ 4, 7, French ¶ ¶ 7, 16; Smith ¶ ¶ 20-22). The compound of the Belgian patent differs significantly from claims 5, 40 and 43 of the ' 322 patent. For example, comparing claim 5 and the Belgian patent:

Position	322 Patent Claim 5	Belgian Pat. 595, 385
3	ketone	methoxy
8	saturated	unsaturated
14	saturated	unsaturated
17	ethynyl and hydroxy	ketone
A ring	single unsaturation at the 4 position	triple unsaturation

(Smith ¶ 18).

*4 23. The Belgian Patent Nos. 595,385 to 595,388 relied upon by Ortho were cited to the Patent Office in applications leading to the Smith patents, and Examiner French would have been aware of them. Thus, these patents raise no issue of patentability not considered by the Patent Office in issuing the '322 patent. (Bjorge II, ¶ 5; French ¶ ¶ 4-6).

24. Ortho alleges that the '322 patent is invalid because the compounds claimed therein are "homologs" of known 13-methyl compounds. In an Office Action mailed on or about June 10, 1968, the claims of the '322 patent were rejected initially by the Patent Office as being unpatentable over 13-methyl compounds. That rejection was overcome during prosecution, with the Patent Office determining that the claims of the '322 patent were indeed patentable over that prior art. (Bjorge II ¶ 8).

25. The 13-ethyl gon-4-enes do not occur in nature, and their physiological properties were thus unknown. Surprisingly, unlike other oral contraceptives, norgestrel does not exhibit a first pass effect. Virtually 100% of norgestrel ingested is available for drug action, allowing for a narrower range of plasma concentrations, lower doses of norgestrel, and far more predictable effects that prior art substances. (Goldzieher I ¶ 21-24).

26. I find that, contrary to Ortho's contention, if Ortho is not prevented from entering the market with its norgestimate-containing products prior to the expiration of AHP's '322 patent, Ortho's norgestimate-containing products will have a substantial effect on AHP's market share and pricing structure which could not be fully quantified in dollars, and would inflict immediate and irreparable harm on AHP. (Rachelli ¶ ¶ 27-28).

27. Ortho plans an aggressive and considerably sophisticated marketing campaign to promote the introduction of its norgestimate-containing product, called Ortho-Cyclen. (Hilke 67-68, 75-76). "We will position

the product by both companies [Ortho and McNeil] as the number one product to present, which is the major selling emphasis." (Hilke at 53-54). This marketing campaign is the largest ever planned by Ortho for introduction of an oral contraceptive. "[T]here is more selling emphasis on this product than there has been on any previous [product] launch." (Hilke at 56). (Hilke at 75-76). Ortho expects to provide about 25 million pills to physicians as free samples. (Hilke at 57). In all, Ortho expects sales of norgestimate to total approximately $185 million to $195 million before the end of 1991. (Hilke at 58). Ortho will distribute information comparing its norgestimate to only one other oral contraceptive--AHP's norgestrel.

28. At present, AHP is awaiting FDA approval for AHP's "new generation" synthetic progestin called gestodene which is presently on the market overseas. (Rachelli ¶ 42, Novinski ¶ 12). Gestodene is expected to be approved by the FDA in the third quarter of 1990. (Victoria Dep. 30, 34, Victoria ¶ 18). The early introduction of Ortho's norgestimate may greatly and negatively affect the reception of AHP's gestodene-containing products. (Rachelli ¶ 43-46).

*5 29. I find that Ortho's infringement may also encourage other infringers to attempt to enter the market prior to the expiration of AHP's '322 patent. (Rachelli ¶ 48).

30. Although Ortho asserts it has expended $50 million in developing Ortho-Cyclen, that amount represents expenditures back to at least 1978 (Hilke Tr. 71), and in part, is now being recouped by foreign sales. This investment will not be lost by the entry of a preliminary injunction. Ortho will still be selling its number-one selling Ortho-Novum(R) product and next year will be able to introduce Ortho-Cylen(R).

31. Ortho alleges that the public interest demands the speedy marketing of norgestimate-containing Ortho-Cyclen even before the expiration of AHP's '322 patent, on the basis that Ortho-Cyclen will become the "drug of choice." I find, however, that Ortho's contention that Ortho-Cyclen will become the drug of choice is not supported by sufficient evidence in the record.

32. For its public interest argument, Ortho relies upon the affidavits of several physicians who express a preference for norgestimate. None of these doctors compared oral contraceptives having Ortho's norgestimate with those having Ortho's norethindrone, which is the largest selling oral contraceptive in the United States. Ortho presents no evidence showing differences in androgenicity or lipid profile between norgestimate and norethindrone. Although it is stated that norethindrone is lipid neutral (i.e., leaves baseline lipid levels unchanged) (Kafrissen ¶ 5) compared to the positive lipid profile of norgestimate (raises HDL/LDL level) the differences have not been shown to be significant in any manner nor of a meaningful magnitude compared to normal fluctuations in lipid levels.

33. The statements Ortho submitted by Drs. Knopp, Corson, Derman, and Stubblefield are contrary to FDA findings, particularly regarding women in the 35-40 age range. (Apodaca ¶ ¶ 16-25; Goldzieher II ¶ 17, Victoria Exhibit H).

34. I find that the proposition that oral contraceptives cause cardiovascular diseases has not been scientifically proven (Goldzieher II ¶ 7, and Exhibit A thereto). This same conclusion has been reached by every independent agency review of the issue, including the United States Food and Drug Administration (FDA) and the Canadian Health Protection branch (HPB) (Goldzieher II ¶ 7).

35. Studies have shown that the risk of heart disease for oral contraceptive users was no greater after eight years of use than after one year. If oral contraceptives, through increased lipid levels, were causing atheroma build-up, one would expect to see that longer use would increase the risk of heart disease. (Goldzieher II ¶ ¶ 13, 14, and Exhibit B thereto.).

36. Ortho makes the statement in its brief that "unlike *any* other oral contraceptive, Ortho-Cyclen actually lowers a patient's undesirable serum cholesterol levels thereby reducing the risk of cardiovascular disease." This statement is scientifically unsound. (Goldzieher II ¶ 16). The changes in lipid profile with different oral contraceptives are small; the differences are well within the ranges deemed acceptable for normal healthy individuals; and the differences in lipid profiles are small compared to the normal variability of the individual and the error range of the testing method. (Goldzieher II ¶ 17, and Exhibit C).

*6 37. Under carefully controlled conditions it was found that coronary plaques in primates taking oral contraceptives actually *decreased.* In other words, the oral contraceptive was cardioprotective. (Goldzieher II ¶ ¶ 18, 19 and Exhibit D thereto). Studies of heart attack patients whose arteries were examined for plaque build-up have shown that those women who had used oral contraceptives showed less extensive plaque build-up than women who had never used oral contraceptives. (Goldzieher II ¶ 20). Accordingly, I find that there is no clinical advantage which would ensue from Ortho-Cyclen(R) compared to the group of oral contraceptives presently being marketed for patients in the high risk

group. (Goldzieher II ¶ 30).

38. The FDA is responsible for regulating the sale of drugs and what can properly be said about their efficacy. The FDA consistently has refused to permit manufacturers of oral contraceptives to claim health benefits due to the lipid profiles accompanying the use of their products. (Goldzieher II ¶ 22, 23).

39. The FDA has not found differences between oral contraceptives to be clinically significant with regard to the actual effect upon those women who take them. (Victoria ¶ ¶ 8, 11, 15, 22-23, 26, Exhibits G and H; Goldzieher II, ¶ 28). The FDA classifies drugs that it reviews by therapeutic potential. Drugs which exhibit an important therapeutic gain are type A. Drugs which only can claim a modest therapeutic gain are type B. Drugs which can claim little or no therapeutic gain--i.e., which are equivalent to drugs already on the market--are type C. Norgestimate is a type C drug, which "essentially duplicates in medical importance and therapeutic usage one or more already marketed drugs." (Apodaca ¶ ¶ 3, 5).

40. Ortho's claim that Ortho-Cyclen shows improved androgenicity over other oral contraceptives is, like their claim of lipid profile, also not approved by the FDA. Practicing physicians can prescribe, from the wide range of oral contraceptives on the market today, oral contraceptives which will minimize androgenic side effects in patients. (Goldzieher II ¶ 29).

II. *CONCLUSIONS OF LAW*

A. *Standards for a Preliminary Injunction.*

41. The Court of Appeals for the Federal Circuit has now made it clear that the standards for considering a preliminary injunction in patent cases are the same as those applied in any other case.

"The standards applied to the grant of a preliminary injunction are no more nor less stringent in patent cases than in other areas of the law."

H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 387 (Fed.Cir.1987):

The standard for preliminary injunction in a patent case is:

[T]o obtain a preliminary injunction, pursuant to 35 U.S.C. § 283, a party must establish a right thereto in light of four factors: (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) the balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest. These factors, taken individually, are not dispositive; rather the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.

*7 *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d at 1451 (footnotes omitted).

Applying this standard, the Federal Circuit has approved the entry of preliminary injunctions in patent cases on a number of occasions. *See, e.g.*, *H.H. Robertson*, 820 F.2d at 384; *Atlas Powder Co. v. Ireco Chem.*, 773 F.2d 1230 (Fed.Cir.1985); *Smith Int'l*, 718 F.2d at 1573; *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d 1446 (Fed.Cir.1988). Note also the following district court decisions: *E.I. duPont De Nemours Co. v. Polaroid Graphics Imaging*, 706 F.Supp. 1135 (D.Del.1989) *aff'd without op.* 887 F.2d 1095 (Fed.Cir.1989); *Southwest Aerospace Corp. v. Teleyne Indus. Inc.*, 702 F.Supp. 870 (N.D. ala 1988), *aff'd without op.* 884 F.2d 1398 (Fed.Cir.1989); *Dreamlite Holdings Ltd. v. Kraser*, 705 F.Supp. 98 (E.D.N.Y.1988) *aff'd without op.* 12 U.S.P.Q.2d 1574 (Fed.Cir.1989); *American Parking Meter Advertising, Inc. v. Visual Media, Inc.*, 693 F.Supp. 1253 (D.Mass 1987) *aff'd without op.* 848 F.2d 1244 (Fed.Cir.1988). *See also Eli Lilly & Co. v. Generix Drug Sales, Inc.*, 460 F.2d 1096 (5th Cir.1972), granting a preliminary injunction in a pharmaceutical case.

B. *Likelihood of Success on the Merits.*

42. The Patent Statute, 35 U.S.C. § 282, is unambiguous:

"A patent shall be presumed valid ... [T]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." A patent is born valid....

Roper Corp. 757 F.2d 1266, at 1270.

43. The infringer's burden of proving invalidity is more difficult to overcome when the evidence relied upon consists only of the prior art considered by the Patent Examiner or when the prior art asserted is no better than that which was before the Examiner when he decided to grant the patent. *Polaroid v. Eastman Kodak Co.*, 789 F.2d 1556, 1560 (Fed.Cir.) *cert. denied*, 479 U.S. 850 (1986); *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1359 (Fed.Cir.1983). *Custom Accessories, Inc. v. Jeffrey-Allan Ind., Inc.*, 807 F.2d 955, 961 (Fed.Cir.1986); *Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 973-74 (Fed.Cir.1986); *E.I. duPont deNemours & Co. v. Polaroid Graphics Imaging, Inc.*, 706 F.Supp. 1135.

44. On a motion for a preliminary injunction, the movant has the burden to show a reasonable likelihood of success on the merits. However, the likelihood of success must be considered in the light that the burden of proving invalidity remains on the challenger. *Roper Corp., supra; American Parking Meter, supra.*

In practical effect, therefore, at the hearing on the motion for the preliminary injunction, Exxon [the infringer] must present clear and convincing evidence of invalidity.

Lubrizol Corp. v. Exxon Corp., 696 F.Supp. 302, 320 (N.D.Ohio 1988).

45. In *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), the Court set forth the basic framework for analyzing obviousness:

Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

*8 46. The marketplace response to a patented invention often provides a significant indication of the non-obviousness of an invention. See *Graham*, 383 U.S. 1, 17-18. In such cases, "secondary considerations" supply objective evidence of how a patent is viewed by those directly interested in a patented product. *Demaco Corp. v. F.V. Langsdorf Licensing Limited*, 851 F.2d 1387, (Fed.Cir.) *cert. denied*, --- U.S. ----, 109 S.Ct. 395 (1988). These secondary considerations, which include commercial success, long-felt need for the invention, failure of others, and acquiescence of the industry, are an essential and integral part of determining obviousness. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1481 (Fed.Cir.1986), *cert. denied*, 482 U.S. 909 (1987); A license indicates a decision to pay tribute to the invention. *See In re Geiger*, 815 F.2d 686 (Fed.Cir.1987).

47. The objective indicia of nonobviousness (the "secondary considerations" of Graham) are usually the most important items of evidence available. *Simmons Fastener Corp. v. Illinois Tool Works*, 739 F.2d 1573, 1575 (Fed.Cir.1984).

"[s]econdary considerations may be the most pertinent, probative, and revealing evidence available to the decision maker in reaching a conclusion on the obviousness/non-obviousness issue.... [U]nder certain circumstances, the evidence of secondary considerations may be particularly strong and entitled to such weight that it may be decisive."

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306 (Fed.Cir.1985), *cert. denied*, 475 U.S. 1017 (1986).

48. Secondary considerations become of utmost importance when considering highly technical information.

Courts, made up of laymen as they must be, are likely to either underrate, or to overrate the difficulties in making new and profitable discoveries in fields with which they cannot be familiar; and, so far as it is available, they had best appraise the originality involved by the circumstances which preceded, attended and succeeded the appearance of the invention.

Safety Car Heating and Lighting Co. v. General Electric Co., 155 F.2d 937, 939 (2d Cir.1946) (L. Hand).

49. For a chemical compound to be obvious, the prior art must teach an obvious method of making that compound. *In re Hoeksema*, 332 F.2d 374 (C.C.P.A.1964). Even if the prior art does teach an obvious method for making a compound, the compound is not obvious if the properties of the compound are not obvious. Chemical compounds and their properties are inseparable and there is no basis in law for ignoring any property in making a comparison. *Jones v. hardy*, 727 F.2d at 1528-1530; *In re Papesch*, 315 F.2d 381 (C.C.P.A.1963).

If the superior property of the new drug has led to its acceptance in the medical community, the compound's superior property is a "significant enough contribution to be deserving of a patent." *United States v. Ciba-Geigy Corp.*, 508 F.Supp. 1157, 1169 (D.N.J.1979).

*9 50. AHP has made a strong showing of objective indicia of non-obviousness supporting the validity of the patent, including (a) the significant and undisputed commercial success of AHP's norgestrel, which falls within the scope of claims 5, 40, and 43; (b) the industry-wide acquiescence for fifteen years in AHP's patent rights, after bitter struggles for priority of invention in the four interferences waged in the Patent Office; (c) the license to Schering AG (Berlex Corporation), again showing the acquiescence of the industry; (d) the fact that the patent Examiner in charge of the case declared that this was one of the most thoroughly prosecuted cases in the history of the Patent Office; and (e) finally, the fact that every new generation oral contraceptive which is coming to market in the United States (Ortho's norgestimate, Schering/AHP's gestodene, and Organon's desogestrel) fall within the scope of the claims of the '322

patent. The references and arguments relied upon by Ortho raise no new issue of patentability; the thorough Patent Office examination has already addressed each of these matters.

51. I find that there is clearly a reasonable likelihood that AHP will prevail on the issue of patent validity, since it is unlikely that Ortho will prove by clear and convincing evidence that the '322 patent is invalid.

C. *Irreparable Harm*

52. The Federal Circuit has enumerated several factors which add to the irreparable harm to a patent owner from infringement. Among these are how well the potential injury to the patentee can be quantified and the fact that "by the time the litigation is finished, it is entirely possible that the value of the patent will be gone...." *Hybritech, Inc.*, 849 F.2d at 1456. *See Augat, Inc. v. John Mezzalingua Assoc., Inc.*, 642 F.Supp. 506, 508 (N.D.N.Y.1986) ("delay operates in clear derogation of the Patent Statute's protection of the right to exclude"). As stated in *American Home Products Corp. v. Abbott Laboratories*, 522 F.Supp. 1035, 1038 (S.D.N.Y.1981), loss of market share constitutes irreparable injury "because market share is so difficult to recover". *See also Lubrizol*, 696 F.Supp. 323.

53. I conclude that, based on the evidence of record in this matter, if Ortho is permitted to embark on its massive, highly sophisticated, and well organized campaign to market its norgestimate-containing products prior to the expiration of AHP's '322 patent in November, 1991, Ortho's norgestimate-containing products will have a substantial deleterious impact on AHP's market share and pricing structure which could never be fully quantified in dollars and which would inflict immediate, as well as continuing, irreparable harm on AHP.

D. *Balance of Hardships*

54. I conclude that the hardship Ortho will suffer by virtue of costs it has incurred in developing and preparing to market an infringing product are attributable solely to Ortho's calculated decision to bring norgestimate to market prematurely, in the face of knowledge that norgestimate infringes the ' 322 patent.

*10 One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected.

Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 n. 12 (Fed.Cir.1986).

55. Ortho's sole allegation of damage is that its return on an investment of about 50 Million dollars will be deferred for about 20 months. On the other side of the balancing scale, there is little question but that AHP will suffer lost sales and market share, lost opportunities for new patients, and harm to its incipient new business in gestodene.

56. In addition, even if Ortho were to suffer more harm for the short period, and I do not believe that they would, the special protection offered by a patent makes a refusal to enjoin activity, later found to be of an infringing nature, an unacceptable involuntary license from the patentee. *American Parking Meter, supra.*

57. A compulsory license, which may arise from a refusal to enjoin, is fundamentally at odds with the right of exclusion built into our patent system. Article I, section 8 of the Constitution grants Congress "the power ... to promote the progress of ... [the] useful arts, by securing for limited times to ... inventors the exclusive right to their ... discoveries." That exclusive right, the right to exclude others from practicing one's invention, is the essence of the patent system.

It is well-settled that, because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole. The patent statute provides injunctive relief to preserve the legal interests of the parties against future infringement which may have market effects never fully compensable in money. "If monetary relief were the sole relief afforded by the patent statute then injunctions would be unnecessary and infringers could become compulsory licensees for as long as the litigation lasts."

Hybritech v. Abbott, 849 F.2d 1446 (Fed.Cir.1988); *American Parking Meter, supra.*

58. Accordingly, I conclude that the balance of hardships on defendant's motion for a preliminary injunction clearly tip in defendant's favor given the circumstances presented in this matter.

E. *Public Interest*

59. The policy rationales behind the patent statutes are equally compelling when applied to controversies involving drug patents. It is in the public interest to protect the pharmaceutical industry's investment into the discovery of new drugs. *Eli Lilly and Co. v. Premo Pharmaceutical Laboratories*, 630 F.2d at 137-38.

There is a strong public interest in upholding and enforcing valid patents. If a patent holder cannot rely on its patent to exclude others then "research and development budgets in the science and technology based industries would shrink, resulting in the public no longer benefitting from the labors of these talented people." *E.I. duPont deNemours & Co. v. Polaroid Graphics Imaging, Inc.*, 706 F.Supp. at 1146.

*11 60. In the present case, I find that AHP has demonstrated: (1) a reasonable likelihood of success on the merits; (2) a clear showing of irreparable harm to the movant; and (3) a balance of hardships which decidedly tilts in favor of the movant, all strongly favoring the grant of a preliminary injunction. Finally, the public interest assertions of the accused infringer must be weighed against the public interest in enforcing a valid patent.

Ortho has predicated its public interest argument on the alleged superiority of Ortho-Cyclen on the grounds that the positive effect on the lipid profile provided by Ortho-Cyclen is purportedly not available from any other oral contraceptive product available in the United States. Furthermore, Ortho contends that the Declarations of Drs. Derman, Corson, Stubblefield and Knopp all attest to the desirability of Ortho-Cyclen from a doctor's perspective. Ortho argues that "unlike *any* other oral contraceptive, Ortho-Cyclen actually lowers a patient's undesirable serum cholesterol levels thereby reducing the risk of cardiovascular disease." However, I find that Ortho's assertion in this regard is contradicted by the evidence presented in this case thus far. The changes in lipid profile with different oral contraceptives are small; the differences are well within the ranges deemed acceptable for normal healthy individuals; and the differences in lipid profiles are small compared to the normal variability of the individual and the error range of the testing method. (Goldzieher II ¶ 17, and Exhibit C). The FDA has not found differences between oral contraceptives to be clinically significant with regard to the actual effect upon those women who take them. (Victoria ¶ ¶ 8, 11, 15, 22-23, 26, Exhibits G and H; Goldzieher II, ¶ 28). As discussed earlier, the FDA classifies drugs that it reviews by therapeutic potential. Drugs which exhibit an important therapeutic gain are classified as Type A drugs. Drugs which only can claim--a modest therapeutic gain are Type B. And drugs which can claim little or no therapeutic gain--i.e., which are equivalent to drugs already on the market--are Type C. Norgestimate has been classified as a Type C drug, which "essentially duplicates in medical importance and therapeutic usage one or more already marketed drugs." (Apodaca ¶ ¶ 3, 5). Accordingly, I conclude that there is no clinical advantage which would ensue from Ortho-Cyclen compared to the group of oral contraceptives presently being marketed for patients.

The public interest argument advocated by Ortho, when weighed against the public interest in upholding and enforcing still valid patents that have yet to be proven invalid by clear and convincing evidence, is insufficient to deny defendant AHP's motion for a preliminary injunction. I therefore conclude that there is no "critical public interest that would be impaired by the grant of preliminary relief." *Hybritech Inc. v. Abbott Laboratories*, 845 F.2d at 1458.

61. No one of the four elements considered on a motion for a preliminary injunction should be dispositive: there must be a balance between the four factors. *H.H. Robertson*, 820 F.2d at 390-91. Where, as here, AHP has shown that it is likely to succeed on the merits; that it will suffer irreparable harm if preliminary relief is not granted; that the balance of hardships tilts in favor of AHP; and that the public interest is best served by enforcing a valid United States patent a preliminary injunction should issue to preserve the status quo to prevent future trespass. *Id.*

*12 An appropriate Order follows.

ORDER

AND NOW, this 23rd day of February, 1990, upon consideration of defendant American Home Products Corporation's Motion for a Preliminary Injunction, the supporting materials filed therewith, the response by plaintiff Ortho Pharmaceutical Corporation, and upon conclusion of a Hearing on the defendant's motion held February 21, 1990, and in accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby Ordered that defendant's motion is GRANTED and that plaintiff Ortho Pharmaceutical Corporation is ENJOINED from making, using or selling any product containing the chemical compound norgestimate and alleged to be in violation of defendant American Home Product's '322 Patent until the expiration of defendant's '322 Patent in November of 1991.

It is further Ordered and Directed that the defendant shall file a corporate surety bond within ten days from the date of this Order and in no event later than March 6, 1990, in such form and amount as the parties may agree upon or, in the event of their failure so to agree, in the form and amount fixed by the Court in a subsequent Order.

AND IT IS SO ORDERED.

FN1. The '911 patent is not in issue on this motion.

1990 WL 18681 (E.D.Pa.), 15 U.S.P.Q.2d 1856

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